AMENDMENTS TO THE CLAIMS

(Currently Amended) A process of preparing cells for cell therapy, comprising the 1. steps of:

inducing helper T Th cells that have a nonspecific antitumor activity; and imparting antigen specificity to the helper T Th cells

wherein the step of imparting antigen specificity to the helper T cells is carried out by transducing a T cell receptor gene that recognizes a cancer-associated antigen.

2 (Cancelled)

- (Currently Amended) The process for preparing cells for cell therapy according to 3. claim 1, wherein the step of imparting antigen specificity to the helper T Th cells is carried out by transducing a gene for a class I-restricted T cell receptor gene TCR that recognizes a cancerassociated antigen.
- (Currently Amended) The process for preparing cells for cell therapy according to claim 1, wherein the step of imparting antigen specificity to the helper T Th cells is carried out by transducing a gene for a class II-restricted T cell receptor gene TCR that recognizes a cancerassociated antigen.
- (Currently Amended) The process for preparing cells for cell therapy according to any 5. of claims 1, 3 or 4 2 to 4, wherein the cancer-associated antigen is selected from the group 2

consisting of Wilms' Tumor 1 WT1, CEA, AFP, CA19-9, CA125, PSA, CA72-4, SCC, MK-1, MUC-1, p53, HER2, G250, gp-100, MAGE, BAGE, SART, MART, MYCN, BCR-ABL, TRP, LAGE, GAGE, and NY-ESO1.

- 6. (Currently Amended) The process for preparing cells for cell therapy according to claim 1, wherein the step of inducing helper T Th cells having a nonspecific antitumor activity is carried out by culturing a T cell-containing material in the presence of anti-CD3 antibody and IL-2.
- 7. (Currently Amended) The process for preparing cells for cell therapy according to any of claims 1, 3, 4 or 6 1 to 6, further comprising a step of purifying the helper T The cells to which antigen specificity has been imparted.
- 8. (Currently Amended) The process for preparing cells for cell therapy according to claim 7, wherein the step of purifying the <u>helper T</u> Th cells to which antigen specificity has been imparted is carried out by using antibody-bearing magnetic beads.
- (Currently Amended) A process of preparing cells for cell therapy, comprising the steps of:

inducing <u>helper T 1</u> Th1 cells and <u>cytotoxic T 1</u> Te1 cells that have a nonspecific antitumor activity; and

Application No. 10/583,860 Reply to Office Action of September 16, 2008

imparting antigen specificity to the <u>helper T 1</u> Th+ cells and <u>cytotoxic T 1</u> Te+ cells wherein the step of imparting antigen specificity to the helper T 1 cells and cytotoxic T 1 cells is carried out by transducing a T cell receptor gene that recognizes a cancer-associated antigen.

10. (Cancelled)

- 11. (Currently Amended) The process for preparing cells for cell therapy according to claim 9, wherein the step of imparting antigen specificity to the helper T 1 That cells and cytotoxic T 1 Tel cells is carried out by transducing a gene for a class I-restricted T cell receptor gene TCR that recognizes a cancer-associated antigen.
- 12. (Currently Amended) The process for preparing cells for cell therapy according to claim 9, wherein the step of imparting antigen specificity to the helper T 1 The cells and cytotoxic T 1 Tel cells is carried out by transducing a gene for a class II-restricted T cell receptor gene TER that recognizes a cancer-associated antigen.
- 13. (Currently Amended) The process for preparing cells for cell therapy according to any of claims 9-to-12-9, 11 or 12, wherein the cancer-associated antigen is selected from the group consisting of Wilms' Tumor 1 WT1, CEA, AFP, CA19-9, CA125, PSA, CA72-4, SCC, MK-1, MUC-1, p53, HER2, G250, gp-100, MAGE, BAGE, SART, MART, MYCN, BCR-ABL, TRP, LAGE, GAGE, and NY-ESO1.

Application No. 10/583,860 Reply to Office Action of September 16, 2008

0/583,860 Docket No.: 3691-0133PUS1

14. (Currently Amended) The process for preparing cells for cell therapy according to

claim 9, wherein the step of inducing helper T 1 Th1 cells and cytotoxic T 1 Te1 cells having a

nonspecific antitumor activity is carried out by culturing a T cell-containing material in the

presence of anti-CD3 antibody, IL-2, and IL-12.

15. (Currently Amended) The process for preparing cells for cell therapy according to any

of claims 9, 11, 12 or 14 9 to 14, further comprising a step of separating the helper T 1 Th1 cells

and cytotoxic T 1 Tel cells to which antigen specificity has been imparted.

16. (Currently Amended) The process for preparing cells for cell therapy according to

claim 15, wherein the process of separating the helper T 1 Th1 cells and cytotoxic T 1 Te1 cells

to which antigen specificity has been imparted is carried out by using antibody-bearing magnetic

beads.

17. (Currently Amended) The process for preparing cells for cell therapy according to

claim 15-or-16, further comprising a step of mixing the separated helper T 1 Th1 cells and

cytotoxic T 1 Te1 cells in any given proportion.

18. (Currently Amended) Cells for cell therapy, that are produced by a process comprising

the steps of:

inducing helper T Th cells that have a nonspecific antitumor activity; and

5

imparting antigen specificity to the helper T Th cells, wherein the step of imparting antigen specificity to the helper T cells is carried out by transducing a T cell receptor gene that recognizes a cancer-associated antigen.

(Currently Amended) Cells for cell therapy, that are produced by a process comprising 19. the steps of:

inducing helper T 1 Th1 cells and cytotoxic T 1 Te1 cells that have a nonspecific antitumor activity; and

imparting antigen specificity to the helper T 1 Th1 cells and cytotoxic T 1 Te1 cells, wherein the step of imparting antigen specificity to the helper T 1 cells and cytotoxic T 1 cells is carried out by transducing a T cell receptor gene that recognizes a cancer-associated antigen.

(Currently Amended) A method for preventing or treating tumor, comprising the steps 20. of:

isolating leukocytes from a patient;

inducing from the leukocytes helper T Th cells that have a nonspecific antitumor activity; imparting antigen specificity to the helper T Th cells, wherein the step of imparting antigen specificity to the helper T cells is carried out by transducing a T cell receptor gene that recognizes a cancer-associated antigen; and

administering to the patient the helper T Th cells to which antigen specificity has been imparted.

 (Currently Amended) A method for preventing or treating tumor, comprising the steps of:

isolating leukocytes from a patient;

inducing from the leukocytes <u>helper T 1</u> Th1 cells and <u>cytotoxic T 1</u> Te1 cells that have a nonspecific antitumor activity;

imparting antigen specificity to the helper T 1 That cells and cells and cytotoxic T 1 Teel cells, wherein the step of imparting antigen specificity to the helper T 1 cells and cytotoxic T 1 cells is carried out by transducing a T cell receptor gene that recognizes a cancer-associated antigen; and administering to the patient the helper T 1 That cells and cytotoxic T 1 Teal cells to which antigen specificity has been imparted.